EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Records and Archives

SOP Number: ADM-03-02

Date Revised: 08-25-05

Initiated By: _____ Date: ___/___/___

Print Name_____

Technical Review: _____ Date: ___/___/___

Print Name:_____
Technical Staff

QC Review: _____ Date: ___/___/___

Print Name:_____
QA Officer

Approved By: _____ Date: ___/___/___

Print Name:_____
Branch Chief

Effective Date: _____/_____/_____

Controlled Copy No.: _____

Withdrawn By: _____ Date: ____/_____/____

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1.0 SCOPE AND APPLICATION:

1.1 The purpose of this procedure is to provide guidance for the archiving of records generated by the Office of Pesticide Programs' Microbiology Laboratory located at the Environmental Science Center, Fort Meade, Maryland.

1.2 This procedure applies to all records generated by the lab staff, the quality assurance unit, and the branch chief.

2.0 DEFINITIONS:

2.1 Record: All books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an Agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that Agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value in them (see ref. 15.1).

2.2 Record Schedule: EPA's official policy for records and information retention and disposal which provides mandatory instructions for what to do with records no longer needed for current agency business (see ref. 15.1).

3.0 HEALTH AND SAFETY: Not applicable.

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable.

9.0 SAMPLE HANDLING AND STORAGE: Not applicable.

10.0 PROCEDURE AND ANALYSIS:

10.1 Summary. The archivist appointed by the Lab Director shall be responsible for retaining all records received or generated by the OPP Microbiology Laboratory according to the Agency's records schedule (see ref. 15.2).

10.2 Conformance to Agency's Records Schedule for Laboratory Test Reports. Laboratory test reports for the Office of Pesticide Programs shall be maintained following EPA Series No. 337, Laboratory Test Reports, of the US EPA Records Schedule. Laboratory test reports include product performance test reports, Plant Incorporated Protectant (PIP) program reports, Homeland Security Program reports and other test reports produced by the OPP Microbiology Laboratory (ref. 15.2).

10.2.1 Record Copy: The record copy of laboratory test is the final data report on paper. The record copies shall be arranged by EPA Registration Number in secured file cabinets in the file room D217. Only authorized personnel have access to the secured files. Record copies shall be kept at the ESC for at least 3 years. After 3 years, record copies may be retired to the Federal Record Center due to space limitations. After 10 years, the record copies shall be destroyed.

10.2.2 Electronic Versions of the Record Copy: Electronic versions of the record copy of laboratory test reports created with office automation applications may be deleted when the paper record copy is generated. The retention of the electronic version of the record copy shall not exceed the retention of the paper copy.

10.3 Conformance to Agency's Records Schedule for Supporting Documentation of Laboratory Test Reports. Supporting documentation of laboratory test reports for the Office of Pesticide Programs shall be maintained following EPA Series No. 337, Laboratory Test Reports, of the US EPA Records Schedule. Supporting documentation of laboratory test reports include but is not limited to the following:

1. Media/Reagent Preparation Records
2. Media and Chemical Control Number Records
3. Supply Control Number Records
4. Disinfectant Product Chain-of-Custody
5. Carrier Bioscreening Test Results
6. Carrier Counts for AOAC Use Dilution Test Results

7. AOAC Use Dilution Test Results
8. Carrier Counts for AOAC Confirmatory Tuberculocidal Test Results
9. AOAC Confirmatory Tuberculocidal Test Results
10. Carrier Counts for AOAC Sporicidal Activity Test Results
11. AOAC Sporicidal Activity Test Results
12. Organism Control Records
13. Quality Control Records Including But Not Limited to the Following:
    A. Quality Assurance of Purified Water Records
    B. Performance and Sterility Check of Media Records
    C. Autoclave Sterilization Records
    D. Timers and Hygrometers Calibration Certificates
    E. Buret Calibration Records
    F. Eppendorf Pipette Calibration Records
    G. Point Check Calibration of Laboratory Thermometers Records
    H. Thermometer Calibration Certificates
    I. Temperature Records for Incubators, Refrigerators and Freezers
    J. Air Sampling Monitoring Records
    K. Detergent Residue Test Records
    L. Heterotrophic Bacteria in Recirculating Chillers Records
    M. Records for Laboratory Equipment Including But Not Limited to Autoclaves, CASBA 4, Dishwashers, Microscopes, Spectrophotometers, Spiral Plater and Vitek
14. Quality Assurance Records Including But Not Limited to the Following:
    A. Master Schedule
    B. Standard Operating Procedures (SOPs) and associated forms
    C. Study Protocols
    D. Internal Audits
    E. External Audits
    F. Media Recipe Book
    G. QA Project Plans
    H. Position Descriptions/External Training Records for Staff
    I. Curriculum Vitae (CVs)/Qualifications Maintained in the office of the Branch Chief (D206)
15. State Testing Program-Related Correspondence
16. State Biological Report of Analysis (BRA) Forms and Reviews
17. Plant Incorporated Protectant (PIP) Program Reports
18. Homeland Security Program Reports
19. Other Reports and Assessments Produced by or Related to Work Performed by the OPP Microbiology Laboratory

10.4 Conformance to Agency's Records Schedule for Routine Procurement Files. Routine procurement files for EPA shall be maintained following EPA Series No.

036, Routine Procurement Files, of the US EPA Records Schedule. Routine procurement files include purchase orders, procurement requests, bankcard purchase logs, travel authorizations, shipping bills (e.g., Federal Express Air Bills, etc.) and other files documenting the acquisition of goods and non-personal services by the OPP Microbiology Laboratory (see ref. 15.3).

10.4.1 Transactions Exceeding $2,000: Inactive materials shall be arranged chronologically in secured file cabinets in the file room D217. Only authorized personnel have access to the secured files. Materials shall be kept at the ESC for 6 years, 3 months and then destroyed. Record copies may be retired to the Federal Record Center 1 year after they are inactive if volume warrants.

10.4.2 Transactions at or Below $2,000: Inactive materials shall be arranged chronologically in secured file cabinets in the file room D217. Only authorized personnel have access to the secured files. Materials shall be kept at the ESC for 3 years and then destroyed. Record copies may be retired to the Federal Record Center 1 year after they are inactive if volume warrants.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 All records shall be retained according to the Agency's records schedules and to the policies of the Agency's National Records Management Program.

13.0 QUALITY CONTROL:

13.1 The records management practices of the OPP Microbiology Laboratory conforms to the Agency's records schedules and to the policies of the Agency's National Records Management Program.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any instances of non-compliance with this SOP will be corrected upon discovery.

15.0 REFERENCES:

15.1 US EPA National Records Management Program Website (www.epa.gov/records).

15.2 US EPA Records Schedule, EPA Series No. 337, Laboratory Test Reports.

15.3 US EPA Records Schedule, EPA Series No. 036, Routine Procurement Files.

16.0 FORMS AND DATA SHEETS: None